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Certified by

Jon W Dudas

Acting Under Secretary of Commerce
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This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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☐ *Additional inventors are being named on the _____ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

SURFACE TEXTURING FOR FLUID CONTROL

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☑ Specification *Number of Pages* 8 ☐ CD(s), Number

☑ Drawing(s) *Number of Sheets* 3 ☑ Other (specify) ~~Application Cover Sheet, and Return~~ Postcard

☐ Application Data Sheet. See 37 CFR 1.76

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☑ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check or money order is enclosed to cover the filing fees.

☑ The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 08-1641

☐ Payment by credit card. Form PTO-2038 is attached.

FILING FEE AMOUNT ($): $80.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☑ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE Hao Y. Tung

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Date 9/30/03

REGISTRATION NO. *(If appropriate)* 43,209

Docket Number: 38187-2692

The PTO did not receive the following listed Items(s) Small entity Status

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

Attorney Docket No.: 38187-2692

PROVISIONAL PATENT APPLICATION
SURFACE TEXTURING FOR FLUID CONTROL

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PATENT

Attorney Docket No.: 38187-2692

SURFACE TEXTURING FOR FLUID CONTROL

BACKGROUND OF THE INVENTION

The technical field relates to fluid dynamics and control of fluid flow on surfaces.

Lancing devices are known in the medical health-care products industry for piercing the skin to produce blood for analysis. Biochemical analysis of blood samples is a diagnostic tool for determining clinical information. Many point-of-care tests are performed using capillary whole blood, the most common being monitoring diabetic blood glucose level. Other uses for this method include the analysis of oxygen and coagulation based on Prothrombin time measurement. Typically, a drop of blood for this type of analysis is obtained by making a small incision in the fingertip, creating a small wound, which generates a small blood droplet on the surface of the skin.

Early methods of lancing included piercing or slicing the skin with a needle or razor. Current methods utilize lancing devices that contain a multitude of spring, cam and mass actuators to drive the lancet. These include cantilever springs, diaphragms, coil springs, as well as gravity plumbs used to drive the lancet. Typically, the device is pre-cocked or the user cocks the device. The device is held against the skin and mechanically triggers the ballistic launch of the lancet. The forward movement and depth of skin penetration of the lancet is determined by a mechanical stop and/or dampening, as well as a spring or cam to retract the lancet. Spontaneous blood droplet generation is dependent on reaching the blood capillaries and venuoles, which yield the blood sample.

As lancing devices have become more advanced, so have the sensors used to measure the glucose levels in the blood samples. These analyte sensors now operate using increasing lower volumes of blood sample. Some of these analyte sensors are designed for use with lancing devices that create smaller wounds, which is beneficial in that there is less pain and tissue damage, but also provide less blood to work with. As the required amount of blood decreases, it becomes increasing important to guide the ever shrinking volumes of blood towards the sensor in an efficient manner that does not waste the small volumes of blood.

There are two states that define fluidic path: 1) one is the bulk properties that determine the surface tension, 2) surface tension contact angles. When a patient bleeds

onto an object or collection module, one of the biggest problems is the surface tension. Traditionally, if you want to create fluidics, you want the object to have a hydrophilic surface. However, if you have a flat hydrophilic surface, the blood goes everywhere in a rather uncontrolled manner, wasting it on surfaces that do not provide an analyte measurement.

SUMMARY OF THE INVENTION

The present invention provides solutions for at least some of the drawbacks discussed above. The technical field relates to guiding a fluid sample obtained from the body for analysis. Because of the low fluid volumes envisioned for improved sensing devices, the ability to efficiently guide the small sample volumes to a targeted area is of interest. Specifically, some embodiments of the present invention provide a body fluid sampling device with improved fluid control. Preferably, the improved fluid control is easy to use. At least some of these and other objectives described herein will be met by embodiments of the present invention.

In one aspect, the present invention provides surface texturing that corrals fluid in areas that desire to receive the fluid sample. The texturing may also be used in combination with other surface treatments such as coatings. Texturing, however, it a more permanent solution.

In one embodiment, radial cartridge is provided that has a plurality of penetrating members and a plurality of analyte detecting members where texturing near the detecting members guides the fluid to the members. The texturing may be formed by a variety of techniques as known in the art and can be formed in various geometries.

The present invention is here to allow us to direct very small volumes of fluid, to guide by restricting its flow due to surface texturing.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention provides a solution for body fluid sampling. Specifically, some embodiments of the present invention provides a method for efficiently transporting blood from spontaneous blood generated from a lancing site. Because of the low fluid

volumes envisioned for improved sensing devices, the ability to efficiently guide the small sample volumes to a targeted area is of interest. For some embodiments of the present invention, the fluid guides may be formed on cartridges having both a penetrating member and an analyte detecting member. At least some of these and other objectives described herein will be met by embodiments of the present invention.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed. It may be noted that, as used in the specification and the appended claims, the singular forms "a", "an" and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a material" may include mixtures of materials, reference to "a chamber" may include multiple chambers, and the like. References cited herein are hereby incorporated by reference in their entirety, except to the extent that they conflict with teachings explicitly set forth in this specification.

In this specification and in the claims which follow, reference will be made to a number of terms which shall be defined to have the following meanings:

"Optional" or "optionally" means that the subsequently described circumstance may or may not occur, so that the description includes instances where the circumstance occurs and instances where it does not. For example, if a device optionally contains a feature for analyzing a blood sample, this means that the analysis feature may or may not be present, and, thus, the description includes structures wherein a device possesses the analysis feature and structures wherein the analysis feature is not present.

Figure 1 shows a radial cartridge 20. The cartridge 20 may include a sterility barrier 22 and a substrate 24 having a plurality of analyte detecting members 26. In this embodiment, the cartridge 20 is designed so that blood will enter the fluid chamber 30 and be held there for analysis.

Referring now to Figure 2, a close up view of the sample chamber area 30 is shown. As discussed, it is often desirable to have a hydrophilic surface when trying to create fluid flow. However, as seen in Figure 2, having a flat surface that is hydrophilic may cause the fluid sample 32 to spread all over the sample chamber 30.

In one embodiment of the present invention, surface texturing may be used to address the issue. Texturing may also be combined with chemical surface treatments or other surface treatments. To design the texture, one may need to account for the surface tension (contact angle): there are the bulk properties (density, etc..) and then there is

another region of interest (surface flow). Since the volumes that the present invention deals with are, as a nonlimiting example, in the area of about 250-500nl, just having blood flow around, is something that the device cannot afford. The fluid flow needs to be a shaped flow, because the fluid cannot be wasted.

At low volumes, there is no conservation and the blood goes everywhere. Let's suppose the blood goes into a tube, but the preferential path is the surface and until the tube fill completely and creates a pressure differential, the blood is not all going in there. The blood could try to pull but the fluid could "break" and then not all of the blood is pulled into the device.

In one embodiment, the present invention essentially involves texturing to direct the flow. This is a solution for tubular designs (capillary tube). Playing with the flow equation allows us to design the texturting...but meshes are different animals since they create increased surface area. The tubular problem are dealing with, such as guiding fluid into a sensor area or a capillary tube involves positioning the fluid to engage the capillary. In one embodiment, a single material is used. The material may be an ideal flow material for use with a single molding. Multiple moldings/laminated moldings may be used. In some embodiments, you go with best material you can get. As a nonlimiting example, materials may have a contact angle in the area of about 20 to 5 degrees.

Figure 3 shows the various geometries that may be used with the present invention. These are purely exemplary and nonlimiting. Additionally, roughing or texturing the surface may improve user feedback, letting them know whether they are on target. It might help with the sensation of contact.

For changing surface property of Teflon and other materials, you can chemically attack it. As an example, the chemical attack may result in about 30 angstroms of surface change. By texturing, it forms and stays in that ring. But in the middle it starts to move into the sensor area (since the other areas are corralled). In some embodiments, a funnel area may be located at center of the "corral". We are affecting the surface properties by texturing.

As a nonlimiting example, the texturing may be used with a typical 300 micron diameter lancet. The blood droplet could form anywhere on the lancet. It's also a C-shaped wound created on the patient. The cutting edge creates that shape. Anywhere around this, droplet can go in the center, or anywhere around the C. That why the texturing is used to corral fluid that may hit the surface and need to be guided. In some

embodiments, there could be gaps in the texturing so that fluid and directed in certain directions.

Types of texturing includes but is not limited to lumpy, bumpy (just texturing) round dots, square dots, etc... Texturing may be formed by any variety of techniques including but not limited to aiming a plasma beam to create the texturing; sacrificial foam/hot press embossing; chemical texturing, combinations of the above, and other techniques as known in the art.

While the invention has been described and illustrated with reference to certain particular embodiments thereof, those skilled in the art will appreciate that various adaptations, changes, modifications, substitutions, deletions, or additions of procedures and protocols may be made without departing from the spirit and scope of the invention. For example, with any of the above embodiments, the location of the penetrating member drive device may be varied, relative to the penetrating members or the cartridge. With any of the above embodiments, the penetrating member tips may be uncovered during actuation (i.e. penetrating members do not pierce the penetrating member enclosure or protective foil during launch). With any of the above embodiments, the penetrating members may be a bare penetrating member during launch. With any of the above embodiments, the penetrating members may be bare penetrating members prior to launch as this may allow for significantly tighter densities of penetrating members. In some embodiments, the penetrating members may be bent, curved, textured, shaped, or otherwise treated at a proximal end or area to facilitate handling by an actuator. The penetrating member may be configured to have a notch or groove to facilitate coupling to a gripper. The notch or groove may be formed along an elongate portion of the penetrating member. With any of the above embodiments, the cavity may be on the bottom or the top of the cartridge, with the gripper on the other side. In some embodiments, analyte detecting members may be printed on the top, bottom, or side of the cavities. The front end of the cartridge maybe in contact with a user during lancing. The same driver may be used for advancing and retraction of the penetrating member. The penetrating member may have a diameters and length suitable for obtaining the blood volumes described herein. The penetrating member driver may also be in substantially the same plane as the cartridge. The driver may use a through hole or other opening to engage a proximal end of a penetrating member to actuate the penetrating member along a path into and out of the tissue. It should understood that any of the inventions herein

may be used in conjunction with devices disclosed in U.S. Patent Applications Attorney Docket No. 38187-2551, 38187-2608, and 38187-2662.

The publications discussed or cited herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed. All publications, patents, and patent applications mentioned herein are incorporated herein by reference to disclose and describe the structures and/or methods in connection with which the publications are cited.

Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included in the smaller ranges is also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either both of those included limits are also included in the invention.

Expected variations or differences in the results are contemplated in accordance with the objects and practices of the present invention. It is intended, therefore, that the invention be defined by the scope of the claims which follow and that such claims be interpreted as broadly as is reasonable.

WHAT IS CLAIMED IS:

1. A method of controlling fluid flow, the method comprising:

(a) providing a cartridge having a plurality of penetrating members and a plurality of analyte detecting members;

(b) using surface texturing on the cartridge to direct fluid into a desired area on the cartridge.

2. The method of claim 1 wherein said texturing is formed chemcially.

3. The method of claim 1 wherein the surface texturing guides the fluid to an analyte detecting member.

ABSTRACT OF THE DISCLOSURE

A method of controlling body fluid flow is provided. The control involves texturing of the surface to guide the fluid. The texturing may be laid out in a variety of geometries. They may also be used on hydrophilic or non-hydrophilic surfaces. They may be used in combination with surface treatments. They may be used with hydrophobic areas.

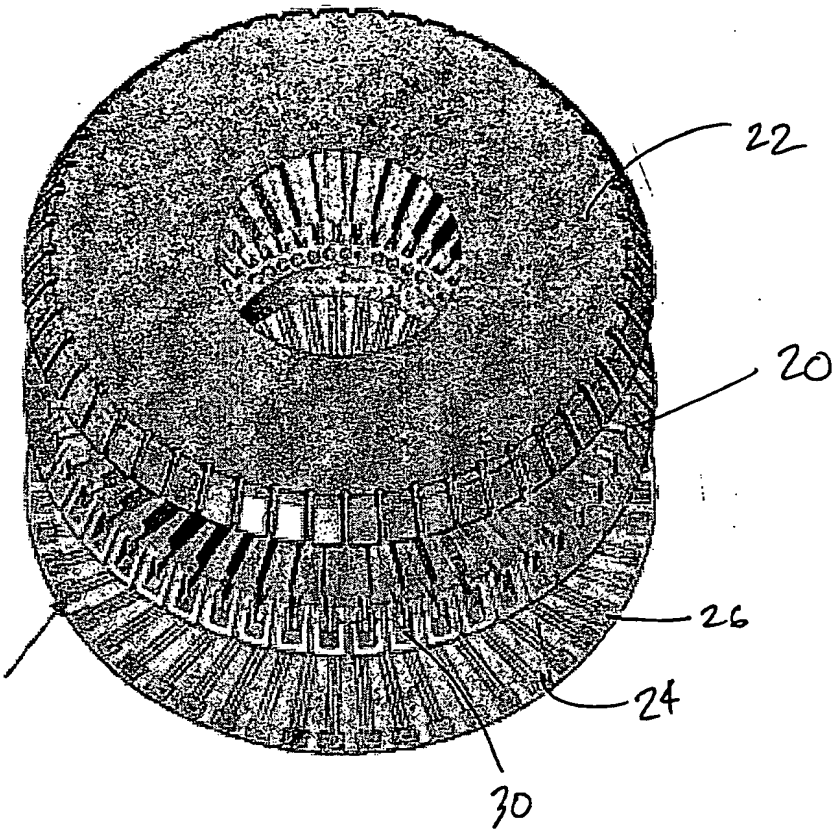


FIG_1

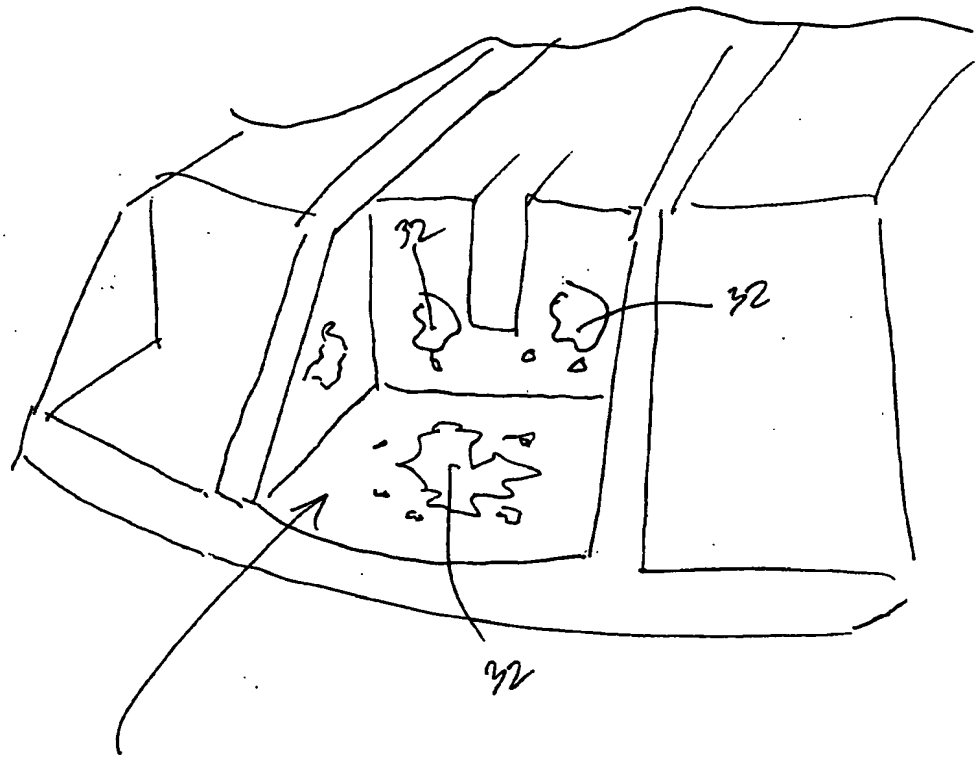
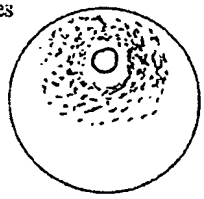
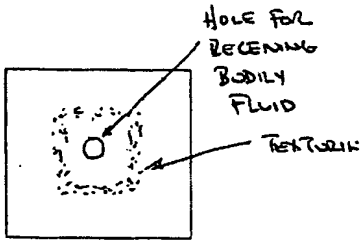


FIG_2

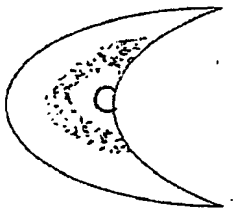
Circular Structures



Box

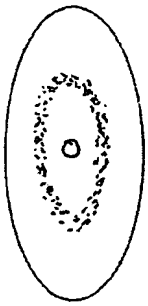


Parabolic

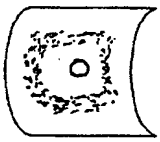


Rectangular

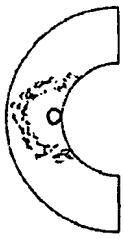
Elliptical



Curved-linear



Horseshoe



Teardrop-heart

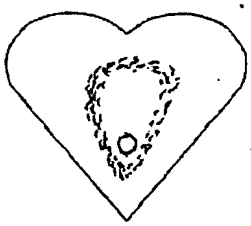


FIG_3

Document made available under the Patent Cooperation Treaty (PCT)

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